UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

DR. REDDY'S LABORATORIES INC.,

Plaintiff,

v.

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, AMARIN CORPORATION PLC

Defendants.

COMPLAINT

Plaintiff Dr. Reddy's Laboratories Inc. ("DRL") brings this antitrust lawsuit against Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation plc (collectively "Amarin" or "Defendants"), by and through its counsel, and alleges as follows:

INTRODUCTION

1. This is an action under the Sherman Act and New Jersey law arising out of Amarin's anticompetitive conduct to delay and prevent generic competition to its branded Vascepa (icosapent ethyl) product. Since it first began marketing Vascepa in 2012, Amarin has embarked on an anticompetitive strategy to insulate Vascepa from generic competition. This is understandable: Vascepa is Amarin's only product, and one for which Amarin has been steadily

increasing prices since its launch. However, Amarin's anticompetitive conduct has delayed generic entry while Amarin overcharges payers and patients.

2. Specifically, DRL has developed its generic icosapent ethyl drug product, prevailed twice in patent litigation with Amarin, and obtained the necessary regulatory approval to market its generic drug. Consequently, there was nothing preventing DRL from launching a generic icosapent ethyl drug product except for Amarin's illegal conduct to foreclose the supply of a critical input to manufacturing—the icosapent ethyl active pharmaceutical ingredient ("API"). Absent Amarin's anticompetitive conduct, DRL would have launched its generic drug product to compete with Amarin's branded Vascepa in August 2020.

3. In particular, after prevailing in patent litigation in district court in March 2020, DRL promptly began preparations for launch, only to discover that Amarin had foreclosed all the suppliers of the icosapent ethyl API who have sufficient capacity to support a commercial launch in a timely manner. First, [redacted]. Indeed, as DRL later discovered, Amarin had entered into a de facto exclusive agreement [redacted]. As a point of comparison, the entire U.S. market for Vascepa is estimated to require only 450 metric tons / year of icosapent ethyl API.

4. [redacted]. But for Amarin's de facto exclusive agreement [redacted], DRL would have been able to obtain the necessary icosapent ethyl API [redacted] and launch its generic icosapent ethyl product as soon as August 2020, when it received the necessary regulatory approval.

5. Second, when [redacted], DRL contacted all potentially viable suppliers of icosapent ethyl API in an attempt to obtain enough supplies to launch as soon as possible. However, DRL's efforts were again thwarted. Since as early as 2012, Amarin had entered into exclusive or de facto exclusive agreements with the only icosapent ethyl API suppliers with sufficient capacity to support a commercial launch of generic icosapent ethyl drug product without having to first expand their capacity. These suppliers are Novasep Holding SAS ("Novasep," including its subsidiary Finorga SAS), Nisshin Pharma Inc. ("Nisshin"), BASF Group ("BASF"), and Chemport Inc. ("Chemport"). Amarin's agreements with these suppliers have a minimum purchase requirement in exchange for exclusivity, and at least some of these agreements also require Amarin to pay the suppliers in cash if it cannot satisfy the minimum purchase requirement in order for the suppliers to maintain exclusivity with Amarin. [redacted]. DRL also reached out to other suppliers who have not entered into exclusive or de facto exclusive contracts with Amarin, but these suppliers all have limited capacity or have not made the requisite regulatory filings, and, thus, they could not supply DRL for the next 1-2 years at the earliest.

6. Amarin's hoarding of icosapent ethyl API supplies is contrary to industry practice, cannot be justified by any legitimate business reason, and can only be explained as part of an

anticompetitive strategy to prevent and delay generic competition to its branded Vascepa. It is industry practice for a branded drug manufacturer to have only one to two API suppliers, even though more may be available, because it is costly to qualify and ensure quality control at the suppliers. Thus, Amarin retaining five API suppliers when there is no indication of supply issues makes no economic sense, and the fact that these contracts are exclusive or de facto in nature is even more suspect. In fact, the evidence suggests that Amarin had sufficient or an excess of API supply. Amarin reportedly stated in December 2018, [redacted], that it had enough API supply for at least two years, totaling $1 billion worth in Vascepa sales. Given Amarin's existing API supplies, it has no legitimate business reason [redacted]. Accordingly, the only explanation for Amarin's various supply agreements is that it has been paying API suppliers to not supply to generic competitors, including DRL, either through literal exclusive agreements or through agreements that allow Amarin to effectively acquire all available supplies of the respective API suppliers.

7. Amarin's exclusive or de facto exclusive agreements, [redacted], foreclosed a substantial part of the market for the supply of icosapent ethyl API. Because of Amarin's conduct, DRL's launch is delayed despite DRL's best efforts to find an alternative API supplier, as the other API suppliers all have limited capacity or have not made the requisite regulatory filings and, thus, could not support a timely launch by DRL. Accordingly, Amarin's various exclusive or de facto exclusive agreements with icosapent ethyl API suppliers have delayed generic competition from DRL. This delay is particularly egregious because there was no legal or regulatory hurdle preventing DRL from launching as of August 2020, and DRL has been prepared to launch as soon as the requisite icosapent ethyl API became available.

8. But for Amarin's locking up of the icosapent ethyl API supply, DRL would have been ready, willing, and able to launch in August 2020, upon receiving regulatory approval. Instead, Amarin's [redacted] and the other icosapent ethyl API suppliers have delayed DRL's launch by a minimum of 10 months, and delayed a launch that will cover the demand for which DRL had set forth resources and planned to meet absent Amarin's anticompetitive conduct by more than a year. In particular, had Amarin not entered into a de facto exclusive agreement [redacted], DRL would have been able to obtain the necessary icosapent ethyl API [redacted] to launch in August 2020. However, Amarin's conduct [redacted] from supplying any meaningful quantity of icosapent ethyl API for DRL to launch in a timely manner.[1]

9. In addition, because Amarin has foreclosed a substantial share of the supply for icosapent ethyl API, DRL was forced to incur additional significant costs to qualify an additional alternative API supplier that had not, amongst other things, made the requisite regulatory filings. DRL cannot commercially market its generic icosapent ethyl drug product using this alternative API supplier until more than a year after when DRL would have launched but for Amarin's anticompetitive conduct.

10. DRL seeks in this action to obtain an order requiring Amarin to cease its unlawful exclusive or de facto exclusive agreements, including [redacted], to recover DRL's lost profits from the delayed launch, treble damages, and an award of DRL's costs and attorneys' fees.

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[1] [redacted] has delayed DRL's launch by more than a year.

PARTIES

11. Plaintiff Dr. Reddy's Laboratories Inc. is a company organized and existing under the laws of New Jersey with its principal place of business in Princeton, New Jersey.

12. On information and belief, Defendant Amarin Pharma, Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 1430 Route 206, Bedminster, NJ 07921.

13. On information and belief, Defendant Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

14. On information and belief, Defendant Amarin Corporation plc is a company incorporated under the laws of England and Wales with principal executive offices at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, Ireland.

JURISDICTION AND VENUE

15. This action arises under the antitrust laws of the United States, including Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, the New Jersey Antitrust Act, N.J. Stat. § 56:9, and New Jersey common law.

16. The actions complained of have occurred in and substantially affected interstate commerce. Specifically, Amarin is engaged in interstate commerce and in activities substantially affecting interstate commerce. Amarin's conduct alleged herein has a substantial effect on interstate commerce. Amarin purchases icosapent ethyl API in interstate commerce and Amarin's products are marketed and sold in all states and territories of the United States. Drug wholesalers and, ultimately, patients across the country purchase Amarin's drugs, including Vascepa.

17. Defendant may be found in, transacts business in, is headquartered in, and is subject to personal jurisdiction in the District of New Jersey.

18. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. §§ 15 and 26. This Court has supplemental subject matter jurisdiction over the New Jersey state law claims pursuant to 28 U.S.C. § 1367(a).

19. The violations of law alleged in this Complaint took place, in part, and have injured DRL in this judicial district. Venue is therefore proper in the District of New Jersey pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391.

STATEMENT OF FACTS

I. STATUTORY AND REGULATORY BACKGROUND

A. Hatch-Waxman Framework

20. The Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the "Hatch-Waxman Act," requires approval by the Food and Drug Administration ("FDA") before a company may market or sell a branded or generic pharmaceutical product in the United States. The overarching purpose of the Hatch-Waxman Act is to balance the preservation of brand pharmaceutical companies' incentives to innovate with the public interest in access to lower-cost, high-quality generic drugs through the creation of a carefully calibrated regulatory framework.

21. To achieve the first goal, the Hatch-Waxman Act provides for multiple types of exclusivity for brand drugs. For example, the Hatch-Waxman Act provides for a five-year exclusivity period for "new chemical entities" ("NCE"), i.e. where the active pharmaceutical ingredient has not been previously approved for any other drug. 21 U.S.C. § 355(c)(3)(E)(ii).

Generic manufacturers are permitted to file their Abbreviated New Drug Applications ("ANDAs") one year before the expiration of the NCE exclusivity.

22. To achieve the second goal of "get[ting] generic drugs into the hands of patients at reasonable prices – fast," *Andrx. Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (internal quotation marks omitted) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)), the Hatch-Waxman Act creates a procedure for generic manufacturers to file ANDAs with the FDA. An ANDA filer need not conduct full clinical trials, as is required for a New Drug Application ("NDA"). Instead, an ANDA filer only has to show that its drug is bioequivalent to the "reference listed drug," typically the brand drug, to demonstrate that the generic product has the same or comparable safety and efficacy as the reference listed drug.

23. Under the Hatch-Waxman Act, NDA holders are required to identify all patents covering the brand drug and such patents' expiration dates in an FDA publication referred to as the "Orange Book." 21 U.S.C. § 355(b)(1) and (c)(2). If an ANDA applicant seeks FDA approval to sell a generic drug before the expiration of the patents listed in the Orange Book as covering the drug, the ANDA must contain a certification that each of the relevant patents "is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Such a certification is known as a "Paragraph IV Certification." The first filer of an ANDA for a product with a Paragraph IV Certification is entitled to 180 days of exclusivity from the first commercial marketing of the drug. 21 U.S.C. § 355(j)(5)(B)(iv)(I). If there are several first filers with the Paragraph IV Certification, the first filers all share the 180-day exclusivity.

24. The filing of a Paragraph IV Certification permits the NDA-holders as well as the holder of any patent identified as purportedly covering the reference listed drug in the Orange Book to bring an action against the ANDA applicant for patent infringement. If such an action is

brought within 45 days from the NDA holder's receipt of the Paragraph IV Certification notification, the FDA is precluded from granting final approval of the ANDA until the earlier of (i) 30 months from the NDA holder's receipt of the Paragraph IV Certification notification; or (ii) the date on which a final judgment is entered in the patent infringement case holding that such patent is invalid, not infringed, or unenforceable.

25. If an ANDA has satisfied all FDA regulatory requirements and the 30-month stay period has not expired or the ANDA applicant is otherwise prevented from launching because of patents, the FDA will grant tentative approval of the ANDA. The ANDA applicant may sell the generic product in the United States only upon receipt of final approval from the FDA, not upon receipt of tentative approval. Conversely, if the ANDA receives final approval, e.g. because the 30-month stay has expired, the ANDA applicant may immediately launch its generic drug regardless of the progress of the patent litigation. If the generic launches while the patent litigation, which may include the appellate process, is on-going, that launch is known as an "at risk" launch.

26. As an alternative to filing a Paragraph IV Certification, if the relevant patents cover only a specific use that the drug is approved for, the ANDA applicant may submit a "Section viii statement" that it is not seeking approval for the use claimed by the patents. 21 U.S.C. § 355(j)(2)(A)(viii). Such a statement is known as a "Section viii carve-out," and a generic drug label approved with a Section viii statement is known as a "carved out" or "skinny" label. Submitting an ANDA with a carved out label does not automatically trigger the patent litigation process described above, and the FDA may approve the carved out ANDA without having to wait. The legality of the FDA approving generic drugs with carved out labels has been upheld by the courts. *See, e.g.*, *Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F. 3d 141, 147-48 (4th Cir. 2002); *Bristol-Myers Squibb Co. v. Shalala*, 91 F. 3d 1493, 1500 (D.C. Cir. 1996).

B. Benefits of Generic Competition

27. Generic drugs typically are sold at substantial discounts from the price of the brand drug. The first generic drug that enters the market generally is priced at a significant discount to the brand drug and, as additional generic drugs enter the market, generic drug prices may fall to as low as 5% of the brand drug's price. A 2017 study commissioned by the Association for Accessible Medicines ("AAM") found that while brand drug prices generally increased by over 200% between 2008 and 2016, generic drug prices generally decreased by approximately 75% during this period.

28. Because generic drugs are typically priced substantially lower than the brand drug price, in a competitive market, they typically take substantial market share from the corresponding brand drugs upon launch, with the proportion of patients and payers switching to the generic drug increasing over time. The increase in the volume that generic drugs take from their corresponding brand drugs means that the savings that generic drugs provide increase over time.

29. Generic drug competition generates large savings for consumers and federal, state, and private payers. "Payers" include health plans and pharmacy benefits managers. A 2004 FDA study found that consumers whose needs can be fully satisfied with generic drugs could enjoy reductions of 52% in their daily medication costs. More recently, the 2017 AAM study found that generic drugs generated savings of $1.67 trillion for the U.S. health care system between 2007 and 2016.

30. Generic savings have steadily increased from $8-10 billion in 1994, as found by a 1998 Congressional Budget Office Report, to $253 billion in 2016, as found by the 2017 AAM study. Within the $253 billion in savings from generic drugs in 2016, Medicaid savings constituted $37.9 billion, and Medicare savings constituted $77 billion. The 2017 AAM study also cites to industry data showing that generic drugs account for 89% of prescriptions, but only 26% of the

costs. Similarly, the 2016 Report to Congress on "Prescription Drugs: Innovation, Spending, and Patient Access" from the U.S. Department of Health and Human Services unequivocally states: "Generic drugs account for the majority of dispensed prescriptions, but a relatively small percentage of spending."[2]

C. Supply and Use of API in Drug Products

31. Brand and generic manufacturers ordinarily purchase the API for their drugs from API suppliers. The manufacturers combine the API with inactive ingredients and process the drugs into their final dosage form. The API for a brand drug and its generic equivalent is typically the same.

32. To sell an API in the United States, the API supplier typically needs to file a Drug Master File ("DMF") with the FDA. The DMF provides confidential and detailed information about, among other things, the facilities and processes used to manufacture, process, package, and store the API. To use an API for a specific drug, a manufacturer must reference the API supplier's DMF in its application for approval filed with the FDA. More than one manufacturer can reference the DMF of the same API supplier. As part of its review of an NDA or ANDA, the FDA would need to perform a complete review of the technical information contained in the DMF referenced therein, including, among other things, inspecting the facilities described in the DMF.

33. The entire process, from API development to FDA approval for use of that API supplier's DMF in support of an NDA or ANDA, ordinarily takes more than a year to complete, and can extend to as long as three years. External factors, such as travel restrictions in response to

[2] U.S. Dep't of Health and Hum. Servs., Prescription Drugs: Innovation, Spending, and Patient Access, at 8 (2016).

the current COVID-19 pandemic, can further delay the FDA's ability to inspect the API supplier's facilities and otherwise delay its review and approval of the use of the DMF.

34. If a manufacturer wants or needs to change its API supplier for a drug, it must file a supplement with the FDA referencing the new API supplier's DMF and submit data for drug batches using the new supplier's API. The manufacturer may only market its drug using the new supplier's API if the FDA approves of the change. FDA review and approval of the change in API supplier can take 6 months or more from the time the new DMF is referenced in the NDA or ANDA.

35. Generic drug manufacturers typically use API from API suppliers that already have a DMF on file and reference that DMF in their ANDAs, as opposed to partnering with API suppliers that have not filed a DMF yet. However, in some situations, such as where all API suppliers with a DMF on file are unable or unwilling to supply to a generic manufacturer, the generic manufacturer may need to work with a new API supplier (who does not yet have a DMF on file) to develop the API for a specific drug. This collaboration process may include the generic manufacturer providing specifications, information and data to the API supplier; co-developing the API; and overseeing the quality control for the process throughout the development of the API. Such collaborative relationships, when they happen, are typically entered into as part of an agreement that the API would be used in that generic manufacturer's drug.

36. Generally, because of the significant costs involved in qualifying an API supplier as well as the need to continue to ensure quality control by the API supplier, it is industry practice for both brand and generic drug manufacturers to use only one or two API suppliers to support a drug application. Where there are concerns about ensuring the adequate supply of API for a drug, a manufacturer may enter into an exclusive supply contract with an API supplier. Conversely, an

exclusive supply contract is unnecessary if there is no concern about API supplies. It is unusual and contrary to industry practice for brand and generic manufacturers to have multiple exclusive API supply contracts. Moreover, it is contrary to industry practice for brand and generic manufacturers to acquire significant excess API supplies due to, among other things, the costs of acquisition and storage as well as quality control issues.

II. VASCEPA

37. Vascepa is the brand name for the icosapent ethyl drug product marketed by Amarin. The API for the drug is eicosapentaenoic acid ("EPA" or "icosapent ethyl"), a type of omega-3 fatty acid derived from fish oil.

38. Amarin submitted the NDA for Vascepa on September 25, 2011. The FDA approved the NDA on July 26, 2012. This original approval included only one indication for Vascepa: "as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia." Subsequently, the FDA determined that Vascepa was entitled to NCE exclusivity, *see supra* at I.A., which ran from the NDA approval date to July 26, 2017.

39. Amarin submitted a supplemental NDA for Vascepa on March 28, 2019, seeking approval for an additional indication. The FDA approved the following new indication on December 13, 2019: "as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and [(a)] established cardiovascular disease or [(b)] diabetes mellitus and 2 or more additional risk factors for cardiovascular disease." The new indication is entitled to data exclusivity, which is scheduled to expire on December 13, 2022.

40. Amarin currently markets Vascepa in the 1g and 500mg strengths. The list price for the drug as of September 2020 was $330.98 / 120 count for the 1g strength and $387.24 / 240 count for the 500mg strength. As the daily dose for Vascepa is 4g/day, this translates to $330.98/month for the 1g strength and $387.24/month for the 500mg strength.

41. Since it first received approval to market Vascepa, and in the absence of generic competition, Amarin has been steadily hiking the price of Vascepa. In particular, Amarin increased the price of Vascepa by approximately 51% from 2013 (when Vascepa price listing was first available) to 2017, with the list price in December 2017 at approximately $280/month. Between December 2017 and November 2019, the price increased by approximately 8% to $303.65/month for the 1g strength. Finally, in less than a year since the approval of the new indication, the list price for the 1g strength jumped by 9% to $330.98/month as of September 2020.

42. Vascepa is Amarin's only product, earning it over $427 million in net product revenue in 2019. Amarin's revenues have been growing dramatically over the years, as shown below. In July 2020, Amarin reported "Q1 2020 net total revenue of $155.0 million[, representing an] increase of 112% over Q1 2019."[3] Amarin reported net revenue for the sale of Vascepa in the United States in 2020 to be over $607 million,[4] and further believes that Vascepa total net revenue "will grow to reach multiple billions of dollars" beyond 2020.[5]

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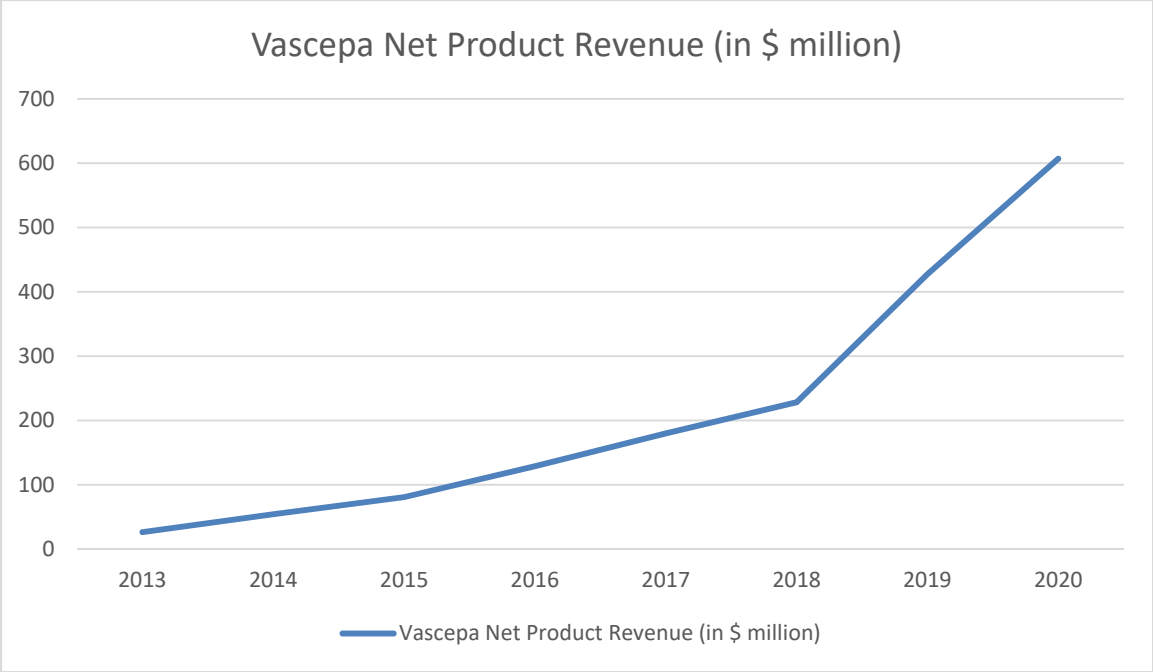
[3] Investor Presentation, Amarin Corp. plc, "Leading a New Paradigm in Cardiovascular Disease Management," at 17 (July 1, 2020).
[4] Amarin Corp. plc, Annual Report (Form 10-K), at F-5 (Feb. 25, 2021).
[5] Press Release, Amarin Corp. plc, "Amarin Receives FDA Approval of VASCEPA® (icosapent ethyl) to Reduce Cardiovascular Risk" (Dec. 13, 2019), https://www.prnewswire.com/news-releases/amarin-receives-fda-approval-of-vascepa-icosapent-ethyl-to-reduce-cardiovascular-risk-300974860.html#:~:text=Beyond%202020%2C%20Amarin%20believes%20that,annual%20revenue%20levels%20beyond%202020..



43. Clearly, the importance of Vascepa to Amarin cannot be overstated. As its president and chief executive officer stated in a company press release, "Amarin's goal is to protect the commercial potential of Vascepa to 2030."[6] And it endeavored to do just that through an anticompetitive strategy to lock up the supply for icosapent ethyl API to prevent generic competition, as described in more detail below.

III. VASCEPA PATENT LITIGATIONS AND APPROVAL OF GENERIC ICOSAPENT ETHYL DRUG PRODUCTS

44. On July 26, 2016, DRL, Teva Pharmaceuticals USA, Inc. ("Teva"), and Hikma Pharmaceuticals USA Inc. ("Hikma") submitted their respective ANDAs for generic icosapent ethyl drug product, all of which contain Paragraph IV Certifications. These companies are the first ANDA filers with Paragraph IV Certifications for generic icosapent ethyl drug product.

[6] Press Release, Amarin Corp. plc, "Amarin Announces FDA New Chemical Entity Market Exclusivity Determination for Vascepa(R) (icosapent ethyl) Capsules" (May 31, 2016), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-fda-new-chemical-entity-market-exclusivity.

45. On October 31, 2016, Amarin filed suit alleging patent infringement against Hikma and its affiliates. On November 4, 2016, Amarin filed suit against DRL. The DRL case was subsequently consolidated into the Hikma case. When Vascepa's new indication was approved in 2019, both Hikma and DRL carved out the 2019-approved indication from their labels, as permitted by the FDCA. *See supra* at I.A. After a bench trial in January 2020, the court issued an order invalidating the asserted patents for obviousness on March 30, 2020. *Amarin Pharma v. Hikma Pharms. USA Inc.*, 449 F. Supp. 3d 967, 971 (D. Nev. 2020), *aff'd*, Nos. 2020-1723, 2020-1901, 2020 U.S. App. LEXIS 28140 (Fed. Cir. Sep. 3, 2020). Amarin appealed the decision, but the Court of Appeals for the Federal Circuit summarily affirmed the district court decision on September 3, 2020, the day after oral argument. The entire order reads: "THIS CAUSE having been heard and considered, it is ORDERED AND ADJUDGED: PER CURIAM **AFFIRMED. See Fed. Cir. R. 36.**" *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, Nos. 2020-1723, 2020-1901, 2020 U.S. App. LEXIS 28140 (Fed. Cir. Sep. 3, 2020) (emphasis in original).

46. In the meantime, the FDA had approved Hikma's ANDA for the 1g strength on May 21, 2020. On August 7, 2020, the FDA also granted final approval to DRL's ANDA for the 1g strength and tentative approval for the 500mg strength. These final approvals removed any remaining legal impediment to launch, which meant that DRL and Hikma were permitted to launch their generics at least for the 1g strength as soon as they were ready. In fact, in November 2020, Hikma announced a launch of its generic icosapent ethyl drug product in limited quantities. As Hikma's chief executive officer explained at a recent J.P. Morgan Healthcare Conference, Hikma's November 2020 launch was in limited quantities because Hikma was "restrained" in building inventory, "and that is linked to the access to the active ingredients." On the other hand, as

explained below, Amarin's anticompetitive locking up of API supplies prevented DRL from launching despite the clearing of all legal and regulatory hurdles.

47. On November 18, 2016, Amarin filed suit against Teva. The case was consolidated into the *Hikma* case, but Amarin and Teva settled the lawsuit on or about May 24, 2018. Amarin's press release stated that Teva is licensed to launch its generic icosapent ethyl drug product on "August 9, 2029, or earlier under certain customary circumstances."[7] A later press release suggested that Amarin did not commit to supplying Teva with icosapent ethyl. On September 11, 2020, the FDA granted final approval for Teva's ANDA.

48. Finally, on information and belief, Apotex Inc. ("Apotex") also filed its icosapent ethyl drug product ANDA in or about July 2016. On information and belief, Apotex's ANDA contained a Paragraph IV Certification as to some, but not all of the patents then listed in the Orange Book for Vascepa. Amarin did not file suit against Apotex in 2016. Apotex amended its ANDA in or about May 2020, making a new Paragraph IV Certification as to all the patents covering the original, 2012-approved indication. On June 16, 2020, Amarin announced that it settled with Apotex, with a licensed launch date of August 9, 2029, the same as the licensed launch date granted to Teva, "or earlier under certain customary circumstances," including if Amarin's appeal from the *Hikma* litigation fails.[8] "The agreement also substantially resolves future litigation with Apotex that could have ensued related to the December 2019 cardiovascular risk reduction

[7] Press Release, Amarin Corp. plc, "Amarin Announces Patent Litigation Settlement Agreement with Teva" (May 24, 2018), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-patent-litigation-settlement-agreement-teva.

[8] Press Release, Amarin Corp. plc, "Amarin Announces Patent Litigation Settlement Agreement with Apotex Inc." (June 16, 2020), https://www.globenewswire.com/news-release/2020/06/16/2049162/0/en/Amarin-Announces-Patent-Litigation-Settlement-Agreement-with-Apotex-Inc.html.

indication . . . . Other terms of the agreement are confidential . . . . In this settlement, consistent with terms of Amarin's 2018 settlement agreement with Teva, Amarin does not commit to supplying Apotex with icosapent ethyl at any time."[9] "Like Teva, any launch by Apotex would be subject to FDA approval of the Apotex ANDA and procurement of adequate supply."[10] Apotex appears not to have received FDA approval for its icosapent ethyl drug product ANDA.

49. Apart from Hikma, which launched with limited quantities in November 2020, the other generic manufacturers, including DRL, have not launched a generic icosapent ethyl drug product yet.

IV. API FOR ICOSAPENT ETHYL DRUG PRODUCT (VASCEPA)

50. As discussed above, the API for Vascepa is EPA, which is derived from fish oil. Another compound derived from fish oil is docosahexaenoic acid ("DHA"), which, together with EPA, forms the API for another fish oil-based drug, Lovaza (omega-3-acid ethyl esters). While both EPA and DHA are derived from fish oil, the API for Vascepa and generic icosapent ethyl drug product cannot be used to manufacture Lovaza and generic omega-3-acid ethyl ester drug products, and vice versa.

51. However, API suppliers of fish oil-based drugs can easily switch capacity to produce the icosapent ethyl API or omega-3-acid ethyl esters API. This is because the raw input (i.e. crude fish oil), facilities, technologies, and manufacturing lines and equipment used to extract and purify the components from fish oil are largely the same for both APIs. These API suppliers can change the manufacturing process, including the isolation and separation processes, to obtain

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[9] *Id.*
[10] Amarin Corp. plc, Quarterly Report (Form 10-Q), at 43 (Nov. 5, 2020).

specific ratios or purities of EPA and DHA, among other specifications, resulting in either the icosapent ethyl API or omega-3-acid ethyl esters API.[11]

52. On the other hand, this ease of switching in terms of manufacturing process does not directly translate to ease of supply of the API to support an ANDA or NDA. An ANDA seeking approval for a generic icosapent ethyl drug product cannot reference an API supplier's DMF for omega-3-acid ethyl esters API, nor can an ANDA seeking approval for generic omega-3-acid ethyl ester drug product reference an API supplier's DMF for icosapent ethyl API. Although an API supplier of fish oil-based APIs can switch its manufacturing process from making the API for

[11]

omega-3-acid ethyl esters to the API for icosapent ethyl, the API supplier must file separate DMFs specific to each of these APIs. Similarly, the ANDA or NDA applicant must submit a supplement to its application if it wants to reference a different DMF. Conversely, if an API supplier already has a DMF for the API for icosapent ethyl, and the ANDA or NDA applicant already referenced that DMF in its application, then the regulatory hurdles are removed. In that case, the API supplier can quickly and easily switch its manufacturing capacity from API for omega-3-acid ethyl esters to support an ANDA or NDA for icosapent ethyl.

V. AMARIN'S ANTICOMPETITIVE LOCKING UP OF ICOSAPENT ETHYL API SUPPLY TO IMPEDE GENERIC COMPETITION

53. Given the importance of Vascepa as Amarin's sole marketed product, it is unsurprising that Amarin has been engaging in a long-standing campaign to insulate Vascepa from competition. In particular, Amarin has been carrying out an anticompetitive strategy to lock up icosapent ethyl API supplies. This includes (a) entering into exclusive or de facto exclusive agreements with at least four of the largest suppliers for icosapent ethyl API, who are the only suppliers apart from [redacted] with sufficient capacity to support a timely commercial launch; and (b) [redacted] that effectively blocks all or substantially all of its capacity for icosapent ethyl API.

54. Amarin's SEC filings describe this anticompetitive strategy well: "Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations in our supply agreements, our suppliers, in certain cases, will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors . . . While we anticipate that intellectual property barriers and FDA regulatory exclusivity will be the primary

means to protect the commercial potential of Vascepa, the availability of Vascepa active pharmaceutical ingredient from our suppliers to our potential competitors would make our competitors' entry into the market easier and more attractive."[12]

55. As a result of Amarin's various exclusive or de facto exclusive agreements, despite a Court of Appeals decision affirming the invalidation of the Vascepa patents and DRL receiving final FDA approval for its icosapent ethyl capsule ANDA, DRL is prevented from launching its generic icosapent ethyl drug product due to the lack of API.

56. Amarin's public statements indicate that the delay to DRL's launch is working as Amarin intended. For example, in its Q1 2020 investors call, Amarin touted: "We have heard from various suppliers that they have been approached regarding supplying API for generic use. These suppliers informed us that they turned down such approaches for various reasons including that they don't have excess capacity." Subsequently, in its August 2020 statements to the investment bank SVB Leerink, Amarin reiterated: "Management's checks with its supplier network do not suggest meaningful capacity being purchased by generic companies." In the same vein, its press release regarding the Court of Appeals decision doubled down on its "assumption" that generic manufacturers "are likely to have limited supply capacity."[13] Amarin's subsequent public statements continued to mention issues regarding the supplies for generic icosapent ethyl products on several occasions. But as described in Amarin's own SEC filings and in more detail below, the lack of API supply capacity for generic manufacturers, including DRL, is caused by Amarin's own

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[12] Amarin Corp. plc, Annual Report (Form 10-K), at 40 (Mar. 3, 2015).
[13] Press Release, Amarin Corp. plc, "Amarin Provides Update Following Ruling in Vascepa® ANDA Patent Litigation" (Sep. 3, 2020), https://investor.amarincorp.com/news-releases/news-release-details/amarin-provides-update-following-ruling-vascepar-anda-patent.

anticompetitive conduct, and the resulting delay to generic competition to Vascepa is working exactly as Amarin intended.

A. Amarin Locked Up a Substantial Share of Icosapent Ethyl API Supply Through Exclusive or De Facto Exclusive Agreements

57. Since it first started marketing Vascepa in the United States in 2012, Amarin had begun its strategy to lock up the supplies for icosapent ethyl API. In particular, Amarin issued a press release on December 11, 2012 stating that it entered into exclusive agreements with a consortium comprising Slanmhor Pharmaceutical, Inc. ("Slanmhor"), Royal DSM N.V., and Novasep. Amarin touted Novasep as "a global leader in purification technologies and API manufacturing."[14] In addition to the exclusive agreement with the Slanmhor/DSM/Novasep consortium, the press release also indicated that Amarin has supply contracts with Nisshin, BASF, and Chemport. Amarin characterized its contracts with these API suppliers as "[p]ooling the resources of four of the world's leading omega-3 API manufacturers."[15]

58. Amarin's description of the capacities of these API suppliers is consistent with their own beliefs and marketing statements, as well as remarks from industry observers. For example, Novasep's website states that it "operates **the largest cGMP purification plant of omega-3 and poly-unsaturated fatty acids in the world**."[16] Further, it operates several manufacturing facilities

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[14] Press Release, Amarin Corp. plc, "Amarin Announces Submission of Supplemental New Drug Application for Novasep as Fourth Vascepa® Active Pharmaceutical Ingredient Supplier" (Aug. 26, 2013), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-submission-supplemental-new-drug-application-2.

[15] Press Release, Amarin Corp. plc, "Amarin Announces Additional Vascepa® (Icosapent Ethyl) Supplier" (Dec. 11, 2012), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-additional-vascepar-icosapent-ethyl-supplier.

[16] Novasep, *Omega 3 poly-unsaturated fatty acids* (last visited Sept. 18, 2020) (emphasis in original), https://www.novasep.com/home/products-services/pharma/generic-and-products/omega-3-6-7.html.

capable of "[l]arge-scale productions from **100's to 1000's tons**."[17] BASF similarly states that it is a "world leader in high-concentrate omega-3 fatty acids for pharmaceuticals, and has leading positions in dietary supplements and clinical nutrition categories."[18] Further, it claims that it is "leading the prescription omega-3 market," with four manufacturing sites in Norway, Scotland, Denmark, and Germany.[19]

59. Amarin's subsequent public discussions and DRL's own communications with these API suppliers confirmed the exclusive nature of Amarin's agreements with them. For example, Amarin's then chief executive officer stated at the 2013 J.P. Morgan Healthcare Conference: "We've established exclusive relationships with leading omega-3 supplies. We have four API suppliers . . . . We've filed the sNDA for a number of additional suppliers and we are looking for that approval."[20] More specifically, Amarin's SEC filings confirmed that its supply agreements with Chemport, BASF, and Slanmhor/DSM/Novasep consortium "include annual purchase levels to enable Amarin to maintain exclusivity with each respective supplier . . ."[21] Moreover, Amarin's agreement with the Slanmhor/DSM/Novasep consortium also contained "a provision requiring [Amarin] to pay Slanmhor in cash for any shortfall in the minimum purchase obligations."[22] That is, Amarin would still need to pay the Slanmhor/DSM/Novasep ***even if***

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[17] *Id.* (emphasis in original).
[18] BASF, *Pioneering in omega-3* (last visited Sept. 18, 2020), https://www.basf.com/global/en/products/segments/nutrition_and_care/nutrition_and_health/omega-3.html.
[19] BASF, *Leading the prescription omega-3 market* (last visited Sept. 18, 2020), https://www.basf.com/global/en/products/segments/nutrition_and_care/nutrition_and_health/omega-3/solutions/pharma.html; BASF, *Production Sites* (last visited Sept. 18, 2020), https://www.basf.com/global/en/products/segments/nutrition_and_care/nutrition_and_health/omega-3/topics/production-sites.html.
[20] *See* Gareth Macdonald, *US approval for omega-3 suppliers BASF and Chemport key for Amarin in 2013*, Outsourcing-Pharma.com (Jan. 11, 2013), https://www.outsourcing-pharma.com/Article/2013/01/10/FDA-OK-for-omega-3-suppliers-BASF-and-Chemport-key-for-Amarin.
[21] Amarin Corp. plc, Quarterly Report (Form 10-Q), at 15 (Aug. 1, 2013).
[22] *Id.*

Amarin does not have enough demand to fill the minimum purchase obligations in order for the consortium to maintain exclusivity with Amarin. Amarin subsequently terminated the agreement with the consortium and entered into a supply agreement with Novasep, which similarly contains the requirement of minimum purchase obligations in exchange for exclusivity, and which requires Amarin to "pay Novasep a cash remedy for any shortfall in the minimum purchase obligations."[23] Amarin also added that the agreement with Chemport contains a similar provision for minimum purchase or cash payment in exchange for exclusivity.[24]

60. [redacted]

61. Amarin's exclusive or de facto exclusive contracts with these leading API suppliers have foreclosed and continue to foreclose a substantial share of the supply for icosapent ethyl API. First, when DRL started developing its icosapent ethyl capsule ANDA in the 2012 timeframe, it reached out to the API suppliers with existing DMFs for icosapent ethyl API at the time. However, these API suppliers all refused to supply API to DRL to support its icosapent ethyl capsule ANDA.

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[23] Amarin Corp. plc, Annual Report (Form 10-K), at 105, F-34 (Feb. 20, 2017).
[24] *Id.*
[25] Amarin's SEC filings until 2018 stated that it had terminated the supply agreement with BASF in February 2014, but that it may enter into a new agreement with BASF, and that BASF remained an FDA-approved API supplier for Amarin.

As a result, while generic manufacturers like DRL ordinarily use API suppliers with existing DMFs and just reference the DMF in their ANDAs, DRL was forced to [redacted]

62. Second, in or about April 2020, [redacted], DRL contacted all known DMF holders for icosapent ethyl API in addition to the four leading suppliers discussed above. However, these other suppliers all stated that they had very limited capacity and/or had no intent to expand their capacity to supply for the U.S. market. The earliest that DRL could launch its generic icosapent ethyl drug product using one of these other API suppliers is 1-2 years, and potentially as long as 3 years, because these API suppliers would need to expand their capacity first. Moreover, DRL cannot obtain timely supply from API suppliers for other omega-3 products who have not filed a DMF specifically for icosapent ethyl API. Use of one of these suppliers would require that supplier to submit a new DMF to FDA that is specific to icosapent ethyl API and require DRL to file a supplement to its ANDA referencing this new DMF.

63. [redacted]X, DRL would have been able to [redacted], complete the necessary regulatory steps, and launch its generic product in 2020 or early 2021. Instead, due to [redacted]

[redacted] API has been delayed by more than a year.

B. Amarin Blocked the Supply of Icosapent Ethyl API to DRL Through [redacted]

64. In addition to foreclosing a substantial part of the supply for icosapent ethyl API through exclusive or de facto exclusive agreements with the four leading suppliers, Amarin also blocked the supply of icosapent ethyl API to DRL through a de facto exclusive agreement [redacted]

65. Specifically, [redacted].

66. [redacted]

67. However, [redacted]

[redacted]

68. [redacted]. As explained above, because the raw materials, facilities, and manufacturing equipment are the same for the omega-3-acid ethyl esters API and icosapent ethyl API, [redacted].

69. There being no legitimate reason for [redacted] but for interference by Amarin. Specifically, [redacted] the omega-3-

acid ethyl esters API. First, omega-3-acid ethyl esters is a highly genericized drug product with ten generics on the market. While this high level of generic competition means that the price of omega-3-acid ethyl esters is lower, it also means that, all else equal, manufacturers of omega-3-acid ethyl esters drug products and its API have depressed margins compared to a drug product with fewer generics on the market. That is the case with icosapent ethyl drug products, which had no generic on the market [redacted] until November 2020, and there are only four known ANDA filers.

70. Second, unlike icosapent ethyl API, there is no shortage of supply for omega-3-acid ethyl esters API, with at least 18 active DMFs on file with FDA. Consequently, icosapent ethyl API provides more opportunity for suppliers to earn higher margins than the omega-3-acid ethyl esters API. Accordingly, it makes no economic sense that [redacted].

71. Third, all else equal, a generic manufacturer launching first will capture more sales than a generic manufacturer launching after another manufacturer has launched. [redacted], DRL had an opportunity to be the first generic to launch, [redacted]. Conversely, if DRL cannot launch early, it is likely to make less sales than if DRL were the first generic to launch. As a result, [redacted].

72. These considerations indicate that [redacted]. The fact that the other icosapent ethyl API suppliers with sufficient capacity also refused to supply DRL

because of exclusive or de facto exclusive agreements with Amarin further suggests that Amarin took action to prevent [redacted].

73. DRL's concerns that Amarin [redacted].

74. [redacted].

75. Thus, after first limiting API supply alternatives through exclusive or de facto exclusive agreements with the four leading suppliers of icosapent ethyl API, Amarin further blocked DRL's ability to launch a competing generic product by [redacted].

VI. AMARIN'S CONDUCT IS CONTRARY TO INDUSTRY PRACTICE, HAS NO LEGITIMATE BUSINESS JUSTIFICATION, AND CAN ONLY BE EXPLAINED AS AN ANTICOMPETITIVE STRATEGY

76. Amarin's four exclusive API supply contracts and [redacted] are contrary to industry practice. As explained above, it is industry practice for a manufacturer, including a brand manufacturer like Amarin, to have one to two API suppliers, even though more may be available, because it is costly and takes a long time to qualify and ensure quality control at the API suppliers. Thus, Amarin's agreements with at least five suppliers, [redacted] is contrary to industry practice and appears economically irrational. This indicates that Amarin entered into these exclusive or de facto exclusive agreements solely to prevent the suppliers from selling API to generic competitors, either through literal exclusivity or through buying up all available supplies.

77. Indeed, Amarin's several exclusive or de facto exclusive agreements with suppliers since 2012 [redacted] cannot be justified by the usual rationale for manufacturers to enter into exclusive supply contracts – i.e. to ensure adequate supplies. Amarin's public statements in December 2018 confirmed that it had enough API supply for at least two years, which was worth $1 billion in Vascepa sales. Moreover, the entire market for Vascepa in the United States is estimated to require 450 metric tons of icosapent ethyl API per year. Amarin's [redacted] is further evidence of Amarin's efforts to lock up icosapent ethyl API supplies, given that it ***already*** has four exclusive suppliers lined up, each a leading supplier of icosapent ethyl API.

78. Accordingly, without any evidence of supply concerns, Amarin has no legitimate justification for entering into the exclusive or de facto exclusive agreements with suppliers and X [redacted]. On the contrary, the evidence clearly indicates that Amarin entered into those agreements to lock up icosapent ethyl API supplies and prevent generic competitors from manufacturing and marketing generic icosapent ethyl drug product.

VII. AMARIN'S CONDUCT HARMS DRL

79. As a result of Amarin's anticompetitive conduct, entry of DRL's generic icosapent ethyl drug product has been substantially delayed by at least 10 months. A launch that will cover the demand for which DRL had set forth resources and planned to meet absent Amarin's anticompetitive conduct was delayed for more than a year. Amarin's strategy is especially effective because the anticompetitive effects of the component agreements feed into and amplify each other, such that the strategy as a whole effectively prevented DRL from launching its competing product in a timely manner despite DRL's best efforts.

80. DRL has successfully developed its generic icosapent ethyl drug product and received FDA approval, and the Court of Appeals for the Federal Circuit has affirmed the invalidation of the relevant Vascepa patents. Further, DRL intends to and is fully prepared to commercially launch its generic icosapent ethyl drug product as soon as possible (which would have been when DRL received FDA approval in August 2020 but for Amarin's anticompetitive conduct). For example, DRL reached out to API suppliers in preparation for commercial launch shortly after winning the patent litigation in district court, before even receiving FDA approval or Court of Appeals affirmation of the litigation win. When [redacted], DRL took all commercially reasonable steps to find alternative supply by contacting all API suppliers holding a DMF for icosapent ethyl API. When these efforts also failed, DRL had to resort to finding a new supplier and partnering with it to develop icosapent ethyl API from start.[26]

[26] DRL is unable to manufacture the API on its own.

81. Nonetheless, despite DRL's best efforts to launch in a timely manner, it is still unable to do so. The only reason why DRL still cannot launch is because Amarin contracted with suppliers of icosapent ethyl API not to sell to generic manufacturers including DRL, either through literal exclusive contract or through buying up all available supplies, such that DRL cannot acquire the necessary API to support a timely commercial launch.

82. In particular, Amarin's [redacted] de facto exclusive agreement [redacted]. Further, Amarin's exclusive or de facto exclusive agreements with the four leading icosapent ethyl API suppliers foreclosed a substantial share of the supply for icosapent ethyl API and prevented DRL from obtaining alternative API supplies sufficient to support a timely launch. This is because the suppliers Amarin has locked up are the only suppliers with sufficient capacity to support a launch without having to first expand their capacity; the other DMF holders for icosapent ethyl API do not have sufficient capacity to support a commercial launch in the next 1-2 years. Thus, Amarin's exclusive or de facto exclusive agreements with the four leading icosapent ethyl API suppliers further delayed DRL's launch and compounded the anticompetitive effect of Amarin's [redacted].

83. But for Amarin's conduct, DRL would have launched as early as when it received FDA approval in August 2020. Amarin's various exclusive or de facto exclusive agreements, [redacted], have delayed DRL's launch of its generic icosapent ethyl drug product by at least 10 months, and delayed a launch that will cover the demand for which DRL had set forth resources and planned to meet absent Amarin's anticompetitive conduct by more than a year. [redacted]

[redacted] is more than a year after when DRL would have launched but for Amarin's anticompetitive conduct.

84. In addition, Amarin's conduct raised DRL's costs by forcing DRL to find an additional alternative API supplier to support its launch. Because of Amarin's conduct, DRL was forced to engage a new API supplier [redacted]. The process for qualifying this API supplier's [redacted] icosapent ethyl API and obtaining regulatory approval has consumed and will continue to consume significant time and resources, thus raising DRL's costs in preparing for its launch. Moreover, the earliest that DRL can launch using this new supplier's API is more than a year after when DRL would have launched absent Amarin's anticompetitive conduct, again resulting in more than a year of lost sales.

MARKET POWER AND RELEVANT MARKETS

85. At all times Amarin has and has maintained monopoly power and market power in the markets for (i) FDA-approved icosapent ethyl drug product ("Icosapent Ethyl Drug Market"), which Amarin markets and sells as the brand product Vascepa (collectively "Icosapent Ethyl Drug Products"); and (ii) the purchase of icosapent ethyl API ("Icosapent Ethyl API Market"). Amarin's monopoly power and market power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market include monopoly power and market power over any narrower markets therein.

86. Icosapent Ethyl Drug Products include AB-rated generic equivalents.

87. Amarin's monopoly power and market power include the ability to control prices and exclude competitors.

88. In the Icosapent Ethyl Drug Market, with respect to Amarin's ability to profitably raise prices, as shown above, a small but significant non-transitory price increase in the price of Vascepa has never resulted in a significant loss of sales, nor would a future small but significant non-transitory price increase result in lost sales. In fact, despite Amarin's consistent price increases for Vascepa over the years, the demand for Icosapent Ethyl Drug Products continues to increase rather than decrease. With respect to Amarin's ability to exclude competitors, direct evidence demonstrates that generic versions of Icosapent Ethyl Drug Products would have more quickly entered the market at substantial discounts to the brand version but for Amarin's anticompetitive conduct.

89. Similarly, in the Icosapent Ethyl API Market, with respect to Amarin's ability to control prices, a small but significant non-transitory decrease in the purchase price of icosapent ethyl API does not and will not result in suppliers of icosapent ethyl API switching to the supply of a different API, including APIs for drugs in the same therapeutic class as Icosapent Ethyl Drug Products. With respect to Amarin's ability to exclude competitors, direct evidence demonstrates that Amarin, through several exclusive or de facto exclusive agreements, successfully precluded generic manufacturers of Icosapent Ethyl Drug Products, including DRL, from purchasing sufficient icosapent ethyl API to commercially launch their generic icosapent ethyl drug products.

90. Amarin did not and does not need to control or influence pricing for any other pharmaceutical product to maintain its monopoly power and market power over Icosapent Ethyl Drug Products and the purchase of icosapent ethyl API.

91. Amarin has sold and continues to sell Icosapent Ethyl Drug Products at a price in excess of any measurement of competitive pricing and in excess of Amarin's marginal cost.

Amarin has experienced atypically high profit margins for Icosapent Ethyl Drug Products, which have been increasing over the years.

92. In addition to direct evidence of monopoly power and market power, indirect evidence also establishes monopoly power and market power. Icosapent Ethyl Drug Products exhibit high barriers to entry, including the costs of developing the product, patent protection, the high cost of entry and expansion, regulatory requirements, and expenditures in marketing and physician detailing. Icosapent ethyl API similarly exhibits high barriers to entry, including the costs of developing the API, patent protection, the high cost of entry and expansion, and regulatory requirements.

93. Until November 2020, Amarin controlled 100% of the Icosapent Ethyl Drug Market. Even after Hikma launched with limited quantities in November 2020, due to the limited nature of the launch, Amarin's market share did not decrease significantly and continues to remain above 85% through present. For example, Amarin's chief executive officer commented that even if Hikma could find "supply capacity to support tens of millions of dollars in revenue [in the near-term] . . . such level would only be a small portion of Amarin's total revenue and even a smaller portion of Vascepa's potential."[27]

94. Similarly, until November 2020, Amarin controlled nearly 100% the Icosapent Ethyl API Market because the volume of icosapent ethyl API that generic manufacturers used for their regulatory submissions is negligible compared to the commercial volume that Amarin purchased. Even after Hikma launched with limited quantities in November 2020, Hikma's

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[27] Seeking Alpha, *Amarin Corporation plc's (AMRN) CEO John Thero on Q2 2020 Results – Earnings Call Transcript* (Aug. 4, 2020), https://seekingalpha.com/article/4364297-amarin-corporation-plcs-amrn-ceo-john-thero-on-q2-2020-results-earnings-call-transcript.

inability to obtain sufficient API to support a full launch forced it to launch in limited quantities, gaining only a 12% share of the Icosapent Ethyl Drug Market. Amarin's share of the Icosapent Ethyl API Market did not decrease significantly through present.

95. Icosapent Ethyl Drug Products are not reasonably interchangeable with any other drugs except for AB-rated generic versions of Icosapent Ethyl Drug Products.

96. Icosapent ethyl API is not reasonably interchangeable with any other API.

97. The existence of other FDA-approved treatments for severe (≥ 500 mg/dL) hypertriglyceridemia has not significantly constrained Amarin, and Amarin has been increasing the prices for Vascepa over the years. For example, Lovaza is indicated for the reduction of triglyceride ("TG") levels in adults with severe (≥ 500 mg/dL) hypertriglyceridemia. Not only did Amarin not reduce the price of Vascepa upon the entry of generic omega-3-acid ethyl esters drug products in 2014, but it continued to increase Vascepa prices in the following years despite generic omega-3-acid ethyl esters drug products' price erosion over time. Even though Vascepa prices were and continue to be higher than the price of generic omega-3-acid ethyl esters drug products, demand for Lovaza and generic omega-3-acid ethyl esters drug products decreased over time whereas demand for Icosapent Ethyl Drug Products increased over time.

98. The existence of other purchasers of fish oil-based API has not significantly constrained Amarin, and Amarin has been maintaining exclusive or de facto exclusive agreements for the supply of icosapent ethyl API with the leading suppliers of fish oil-based API for several years.

99. Manufacturers differentiate brand drugs like Vascepa based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Vascepa. This is due in part

to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Vascepa.

100. Unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the prescribing decision for prescription drugs is made by the prescriber, not consumers of these products.

101. The United States and its territories is the relevant geographic market.

ANTITRUST IMPACT

102. Amarin's anticompetitive strategy to maintain its monopoly in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market through exclusive or de facto exclusive agreements with at least four API suppliers and [redacted], unless remedied, will deny consumers the benefits of generic competition for Vascepa contemplated by the Hatch-Waxman Act. Amarin illegally maintained and extended its monopoly power through exclusionary conduct completely unrelated to its ability to compete on a level playing field.

103. Amarin's anticompetitive conduct has achieved its purpose of preventing and delaying generic competition to Amarin's Vascepa product. By engaging in this conduct, Amarin effectively foreclosed a substantial share of icosapent ethyl API supply. The lack of API supply delays ANDA filers like DRL from launching their generic icosapent ethyl drug product even though there is no legal or regulatory hurdle preventing launch. This delay in competition is exactly what Amarin intended to, and did, cause through its unlawful conduct. During these periods of

delay, consumers are deprived of lower-priced generic icosapent ethyl drug product and are forced to pay higher prices than they would but for Amarin's conduct.

104. Further, had Amarin not foreclosed the only API suppliers with sufficient capacity to support a timely commercial launch without the need to first expand capacity, generic manufacturers would not have had to expend additional significant time and resources to qualify alternative icosapent ethyl API suppliers and obtain regulatory approval. This has prevented the generics from competing on the merits.

105. Amarin's anticompetitive conduct has had a direct, substantial, and adverse effect on DRL and competition by monopolizing and maintaining monopoly power, artificially creating barriers to entry, and foreclosing competition in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. But for Amarin's conduct, DRL would have been able to obtain supply of API [redacted] to launch its generic icosapent ethyl drug product upon receiving FDA approval in August 2020. Alternatively, DRL would have been able to obtain supply of icosapent ethyl API from another supplier, [redacted], in sufficient quantities to launch in 2020 or early 2021. However, because of Amarin's conduct, DRL's launch has been delayed by at least 10 months and a launch that will cover the demand for which DRL had set forth resources and planned to meet absent Amarin's anticompetitive conduct was delayed by more than a year. Additionally, but for Amarin's conduct, DRL would not have needed to divert resources to qualifying a new icosapent ethyl API supplier, and would have applied such resources to more beneficial uses.

106. Amarin's anticompetitive conduct has impeded and continues to impede the sale of generic icosapent ethyl drug product, and thus has allowed, and unless restrained by this Court,

will continue to allow, Amarin to maintain and extend its monopoly power in the relevant markets and to sell Vascepa at artificially inflated monopoly prices.

107. This conduct has harmed the competitive process and allowed Amarin to perpetuate supracompetitive prices against wholesalers, retailers, and consumers. But for Amarin's anticompetitive conduct, consumers and federal, state, and private payers would enjoy the benefits of lower-priced generic competition earlier. Instead, as a result of Amarin's strategies to thwart generic entry, consumers and federal, state, and private payers were and will continue to be forced to pay monopoly rents for Amarin's branded Vascepa. The impact of Amarin's conduct is felt throughout the healthcare industry, impacting pharmaceutical competitors, healthcare providers, insurers and other direct purchasers, intermediaries, and consumers.

108. There is no valid procompetitive business justification for Amarin's anticompetitive conduct, and to the extent Amarin offers one, it is pretextual and not cognizable, and any procompetitive benefits of Amarin's conduct do not outweigh its anticompetitive harms.

COUNT I
SHERMAN ACT SECTION 2 – MONOPOLIZATION

109. DRL repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

110. The Icosapent Ethyl Drug Market and Icosapent Ethyl API Market are the relevant markets.

111. Amarin possesses monopoly power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. These markets are characterized by significant barriers to entry.

112. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

113. Through the foregoing acts, Amarin, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will continue to use, its power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market to monopolize the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

114. Amarin knowingly and intentionally engaged in an anticompetitive strategy designed to unlawfully delay the launch of an AB-rated generic version of Vascepa, and thus to willfully maintain its monopoly power. Specifically, Amarin entered into exclusive or de facto exclusive agreements with at least four leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, and Nisshin—who are also the only suppliers with sufficient capacity to support a timely commercial launch without having to first expand capacity. Further, Amarin entered into a de facto exclusive agreement [redacted].

115. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives to foreclose competition in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. For example, there is no legitimate business rationale for having four API suppliers, contrary to industry practice. Similarly, there is no legitimate business rationale for entering into ***exclusive*** agreements with these four suppliers, and [redacted], as there is no indication of concerns with supplies. To the contrary, the evidence suggests that Amarin already had sufficient

or an excess of API supply from its existing suppliers before [redacted] for the entire Icosapent Ethyl Drug Market. The only justification for these exclusive or de facto exclusive agreements is Amarin's intent to foreclose a substantial share of icosapent ethyl API supply and prevent generic competitors from launching their generic icosapent ethyl drug product.

116. To the extent there are legitimate business justifications for Amarin's exclusionary conduct, Amarin's anticompetitive conduct is not necessary to serve those justifications.

117. By its conduct, Amarin intentionally and wrongfully maintained monopoly power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market in violation of Section 2 of the Sherman Act. As a result of Amarin's unlawful maintenance of monopoly power, DRL has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

118. Amarin's unlawful conduct as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of Icosapent Ethyl Drug Products was restrained, suppressed and eliminated;
- Purchasers of Icosapent Ethyl Drug Products are deprived of the benefits of free and open competition, and the availability of a lower-cost generic icosapent ethyl drug product, in the purchase of Icosapent Ethyl Drug Products; and
- Amarin sold, and will continue to sell, its Vascepa at artificially high and noncompetitive price levels.

119. Amarin's conduct occurred in, and has had a substantial effect on, interstate commerce.

120. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to DRL's business and property, as set forth above. DRL's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

121. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, DRL will suffer immediate and irreparable injury for which DRL is without an adequate remedy at law.

122. DRL is entitled to a judgment that Amarin has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT II
SHERMAN ACT SECTION 2 – ATTEMPT TO MONOPOLIZE

123. DRL repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

124. The Icosapent Ethyl Drug Market and Icosapent Ethyl API Market are the relevant markets.

125. Amarin possesses monopoly power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. These markets are characterized by significant barriers to entry.

126. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by attempting to monopolize the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

127. Through the foregoing acts, Amarin, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will continue to use, its power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market to attempt to monopolize the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

128. Amarin knowingly and intentionally engaged in an anticompetitive strategy designed to unlawfully delay the launch of an AB-rated generic version of Vascepa, and thus to willfully maintain its monopoly power. Specifically, Amarin entered into exclusive or de facto exclusive agreements with at least four leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, and Nisshin—who are also the only suppliers with sufficient capacity to support a timely commercial launch without having to first expand capacity. Further, Amarin entered into a de facto exclusive agreement [redacted].

129. Amarin engaged in this conduct with the specific intent to monopolize the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

130. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives and a specific intent to foreclose competition in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. For example, there is no legitimate business rationale for having four API suppliers, contrary to industry practice. Similarly, there is no legitimate business rationale for entering into ***exclusive*** agreements with these four suppliers, [redacted], as there is no indication of concerns with supplies. To the contrary, the evidence shows that Amarin already had sufficient or an excess of API supply from its existing suppliers before [redacted]

[redacted] for the entire Icosapent Ethyl Drug Market. The only justification for these exclusive or de facto exclusive agreements is Amarin's specific intent to foreclose a substantial share of icosapent ethyl API supply and prevent generic competitors from launching their generic icosapent ethyl drug product.

131. To the extent there are legitimate business justifications for Amarin's exclusionary conduct, Amarin's anticompetitive conduct is not necessary to serve those justifications.

132. Amarin currently enjoys monopoly power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. There is a dangerous probability Amarin will succeed in gaining or maintaining monopoly power by means of its unlawful conduct, as shown by the fact that Amarin's conduct already delayed DRL's launch of its generic icosapent ethyl drug product by at least 10 months and delayed a launch that will cover the demand for which DRL had set forth resources and planned to meet absent Amarin's anticompetitive conduct by more than a year.

133. By its conduct, Amarin intentionally and wrongfully attempted to maintain monopoly power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market in violation of Section 2 of the Sherman Act. As a result of Amarin's unlawful attempted maintenance of monopoly power, DRL has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

134. Amarin's unlawful conduct as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of Icosapent Ethyl Drug Products was restrained, suppressed and eliminated;

- Purchasers of Icosapent Ethyl Drug Products are deprived of the benefits of free and open competition, and the availability of a lower-cost generic icosapent ethyl drug product, in the purchase of Icosapent Ethyl Drug Products; and
- Amarin sold, and will continue to sell, its Vascepa at artificially high and noncompetitive price levels.

135. Amarin's conduct occurred in, and has had a substantial effect on, interstate commerce.

136. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to DRL's business and property, as set forth above. DRL's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

137. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, DRL will suffer immediate and irreparable injury for which DRL is without an adequate remedy at law.

138. DRL is entitled to a judgment that Amarin has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT III
SHERMAN ACT SECTION 1 – CONTRACT, COMBINATION, OR CONSPIRACY IN RESTRAINT OF TRADE

139. DRL repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

140. The Icosapent Ethyl Drug Market and Icosapent Ethyl API Market are the relevant markets.

141. This claim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining and/or agreeing to restrain trade in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

142. Through the foregoing acts, Amarin, unlawfully and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, has acted pursuant to a contract, combination or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

143. Amarin knowingly and intentionally engaged in an anticompetitive strategy designed to unlawfully delay the launch of an AB-rated generic version of Vascepa and thus protect itself from competition. Specifically, Amarin entered into exclusive or de facto exclusive agreements with at least four leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, and Nisshin—who are also the only suppliers with sufficient capacity to support a timely commercial launch without having to first expand capacity. Further, Amarin entered into a de facto exclusive agreement [redacted].

144. Each of these agreements constitute contracts, combinations and conspiracies that substantially, unreasonably, and unduly restrain trade in the relevant markets, and harmed DRL thereby.

145. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives and a desire to foreclose competition in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. For example,

there is no legitimate business rationale for having four API suppliers, contrary to industry practice. Similarly, there is no legitimate business rationale for entering into ***exclusive*** agreements with these four suppliers, [redacted], as there is no indication of concerns with supplies. To the contrary, the evidence shows that Amarin already had sufficient or an excess of API supply from its existing suppliers before [redacted] for the entire Icosapent Ethyl Drug Market. The only justification for these exclusive or de facto exclusive agreements is Amarin's desire to foreclose a substantial share of icosapent ethyl API supply and prevent generic competitors from launching their generic icosapent ethyl drug product.

146. To the extent there are legitimate business justifications for Amarin's exclusionary conduct, Amarin's anticompetitive conduct is not necessary to serve those justifications.

147. By its conduct, Amarin intentionally and unreasonably restrained trade in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market in violation of Section 1 of the Sherman Act. As a result of Amarin's unlawful contracts, combinations and conspiracies, DRL has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

148. Amarin's unlawful contracts, combinations and conspiracies as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of Icosapent Ethyl Drug Products was restrained, suppressed and eliminated;
- Purchasers of Icosapent Ethyl Drug Products are deprived of the benefits of free and open competition, and the availability of a lower-cost generic icosapent ethyl drug product, in the purchase of Icosapent Ethyl Drug Products; and
- Amarin sold, and will continue to sell, its Vascepa at artificially high and noncompetitive price levels.

149. Amarin's conduct occurred in, and has had a substantial effect on, interstate commerce.

150. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to DRL's business and property, as set forth above. DRL's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

151. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, DRL will suffer immediate and irreparable injury for which DRL is without an adequate remedy at law.

152. DRL is entitled to a judgment that Amarin has violated Section 1 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT IV
THE NEW JERSEY ANTITRUST ACT, SECTIONS 56:9-3 AND 56:9-4

153. DRL repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

154. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9 et seq., and seeks a judgment that Amarin's conduct as alleged herein has violated New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4 and § 56:9-3.

Section 56:9-4, Monopolization

155. Amarin's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize, in violation of N.J. Stat. Ann. § 56:9-4.

156. Specifically, Amarin's exclusive or de facto exclusive agreements with at least four leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, and Nisshin—as well as its [redacted], are calculated to maintain monopoly power in the relevant markets, in violation of N.J. Stat. Ann. § 56:9-4.

Section 56:9-3, Agreement in Restraint of Trade

157. Amarin's conduct as alleged herein constitutes a contract, combination, or conspiracy in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

158. Specifically, each of Amarin's exclusive or de facto exclusive agreements with at least four leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, and Nisshin—as well as [redacted] is a contract, combination, and conspiracy in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

* * *

159. Amarin's unlawful contracts, combinations and conspiracies as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of Icosapent Ethyl Drug Products was restrained, suppressed and eliminated;
- Purchasers of Icosapent Ethyl Drug Products are deprived of the benefits of free and open competition, and the availability of a lower-cost generic icosapent ethyl drug product, in the purchase of Icosapent Ethyl Drug Products; and
- Amarin sold, and will continue to sell, its Vascepa at artificially high and noncompetitive price levels.

160. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to DRL's business and property, as set forth above. DRL's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

161. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, DRL will suffer immediate and irreparable injury for which DRL is without an adequate remedy at law.

162. DRL is entitled to a judgment that Amarin has violated Sections 56:9-3 and 56:9-4 of the New Jersey Antitrust Act; to the damages it suffered as a result of that violation, to be trebled in accordance with N.J. Stat. Ann. § 56:9-12, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT V
COMMON LAW OF THE STATE OF NEW JERSEY – UNFAIR COMPETITION

163. DRL repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

164. By reason of the foregoing unlawful, predatory and anticompetitive acts as alleged herein, Amarin has engaged in unfair competition and/or unfair trade practices in violation of the common law of the State of New Jersey.

165. As a result of the foregoing, DRL has been injured in its business and/or property and is entitled to damages, attorneys' fees, costs of suit and other appropriate relief.

COUNT VI
COMMON LAW OF THE STATE OF NEW JERSEY – TORTIOUS INTERFERENCE WITH CONTRACT OR PROSPECTIVE ECONOMIC BENEFIT

166. DRL repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

167. DRL develops and sells pharmaceutical products in the commerce of the State of New Jersey.

168. Amarin's conduct gives rise to common law liability for tortious interference with a contract or prospective economic benefit.

169. [redacted].

170. DRL has a reasonable expectation of prospective economic benefit, i.e. the sufficient supply of icosapent ethyl API, [redacted].

171. Through discovery in Amarin's patent litigation with DRL, Amarin is aware of [redacted].

172. Amarin has intentionally and maliciously interfered with DRL's contractual relationship with and prospective economic benefit [redacted] a de facto exclusive supply agreement [redacted].

173. Amarin engaged in this conduct intentionally and with malice, and does not have a legitimate, procompetitive business justification for entering into this de facto exclusive agreement. Amarin's conduct can only be explained by anticompetitive motives and a desire to interfere with [redacted]. There is no legitimate business rationale for entering into a de facto exclusive agreement [redacted] because there is no indication of concerns with Amarin's supplies. To the contrary, the evidence shows that Amarin

already had sufficient or an excess of API supply from its existing suppliers [redacted] for the entire Icosapent Ethyl Drug Market. The only justification for Amarin's de facto exclusive agreement [redacted].

174. But for Amarin's interference, [redacted], i.e. the sufficient supply of icosapent ethyl API.

175. But for Amarin's interference, there was a reasonable probability that DRL would have received the prospective economic benefit DRL [redacted].

176. DRL also has a reasonable expectation of prospective economic benefit from selling its generic icosapent ethyl drug product to third parties, including distributors, pharmacies, and individuals, who would purchase DRL's generic icosapent ethyl drug product instead of Vascepa.

177. Amarin has been aware of DRL's intention to market a generic icosapent ethyl drug product since at least July 2016. Accordingly, Amarin is aware of DRL's reasonable expectation of prospective economic benefit from sales of generic icosapent ethyl drug product.

178. Amarin has intentionally and maliciously interfered with the prospective economic benefit DRL reasonably expects from sales of generic icosapent ethyl drug product by entering into exclusive or de facto exclusive agreements with at least four leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, and Nisshin—[redacted].

179. Amarin engaged in this conduct intentionally and with malice, and does not have a legitimate, procompetitive business justification for entering into these exclusive or de facto exclusive agreements. Amarin's conduct can only be explained by anticompetitive motives and a desire to interfere with the prospective economic benefit DRL reasonably expects from sales of generic icosapent ethyl drug product. For example, there is no legitimate business rationale for having four API suppliers, contrary to industry practice. Similarly, there is no legitimate business rationale for entering into ***exclusive*** agreements with these four suppliers, [redacted], as there is no indication of concerns with supplies. To the contrary, the evidence shows that Amarin already had sufficient or an excess of API supply from its existing suppliers before [redacted] for the entire Icosapent Ethyl Drug Market. The only justification for Amarin's exclusive or de facto exclusive agreements is Amarin's desire to foreclose a substantial share of icosapent ethyl API supply and prevent DRL from obtaining the

prospective economic benefit DRL reasonably expects from sales of generic icosapent ethyl drug product.

180. But for Amarin's interference, there was a reasonable probability that DRL would have received the prospective economic benefit DRL reasonably expects to receive from sales of its generic icosapent ethyl drug product to third parties, including distributors, pharmacies, and individuals, who would purchase DRL's generic icosapent ethyl drug product instead of Vascepa.

181. Amarin's tortious interference has directly and proximately caused injury to DRL's business and property, including but not limited to lost profits and lost business opportunities.

JURY DEMAND

182. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, DRL demands a trial by jury as to all issues of right to a jury.

PRAYER FOR RELIEF

WHEREFORE, DRL respectfully requests that this Court enter judgment against the Defendants as follows:

a. Permanent mandatory injunctive relief pursuant to 15 U.S.C. § 26, Fed. R. Civ. P. 65, and N.J. Stat. Ann. § 56:9-10, restraining Amarin, its affiliates, successors, transferees, assignees and other officers, directors, partners, agents and employees thereof, from continuing, maintaining or renewing the conduct, contract, conspiracy, or combination alleged herein, or from engaging in any other conduct or entering into any other contract, conspiracy, or combination having a similar purpose or effect;

b. Compensatory damages for DRL's lost sales of generic icosapent ethyl drug product, and profits on those sales, that are caused by DRL's delay in launching its generic icosapent ethyl drug product;

c. Treble damages pursuant to 15 U.S.C. § 15 and N.J. Stat. Ann § 56:9-12;

d. Pre- and post-judgment interest as provided by law;

e. An award of attorneys' fee and costs pursuant to 28 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12; and

f. Such other and further relief as the Court deems just and proper.

Dated: April 27, 2021

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